March 12, 2020

**Informal Semiconductor Industry Association Discussion with EPA on NMP**
**March 12, 2020**

- The Semiconductor Industry Association (SIA) considers the data and information submitted to the Agency sufficient to support the conclusion that the conditions of use of NMP in semiconductor manufacturing do not present an unreasonable risk to workers.

- SIA provided information to EPA on:
    - Container changeout tasks (Semiconductor Industry Association, Nov. 2019, Appendix A pp.6-8, pp.16-17, C-1 thru C-4).
    - Maintenance tasks which may occur in fab, sub-fab or parts clean room (Semiconductor Industry Association, Nov. 2019, Appendix A, pp.9-14, p.17, M-1 thru M-8).
    - Fab Operations – majority of fab workers are occupationally non-exposed workers because processes occur in enclosed tools (Semiconductor Industry Association. Nov. 2019 Appendix A, p. 14, results pp.17-18, F-1 thru F-6; OECD 2010).
    - Truck load/offload (Semiconductor Industry Association, Nov. 2019, Appendix A pp.14-15, results p. 18, T-1).

  Additional estimates of dermal contact and duration of exposures is provided in Semiconductor Industry Association, 2020, Appendix A.

- No opportunities for exposures occur on loading docks where NMP is delivered. NMP is delivered to semiconductor facilities in a variety of container sizes (Semiconductor Industry Association, Nov. 2019, Appendix A pp.6-8, C-1 thru C-4). Chemicals used in semiconductor fabs must be maintained at high purity; thus, containers and drums must remain sealed until use and are not opened on the loading docks. Containers may be opened in fab, sub-fab chemical distribution rooms, or parts clean room by workers wearing appropriate personal protective equipment. Such PPE is described in SIA's November 2019 submission and our 2020 follow-up. Submission by member companies corroborate this information.

- The following tasks may be performed in sub-fab floor spaces where connections to lines/equipment might be made/removed from containers in which NMP is present.
    - Container changeout tasks may be conducted in the fab, sub-fab or chemical distribution rooms (Semiconductor Industry Association, Nov. 2019, Appendix A pp.6-8, pp.16-17, C-1 thru C-4).
    - Maintenance tasks may be in fab, sub-fab or parts clean room (Semiconductor Industry Association. Nov. 2019, Appendix A, pp.9-14, p.17, M-1 thru M-8).

- Additional information on work shift lengths can be found at: Semiconductor Industry Association. Nov. 2019, Appendix A, p.5 and Semiconductor Industry Association, 2020, Appendix A.

- Container handling. During loading and unloading of bulk NMP and waste shipments, engineering controls and PPE are used to minimize worker exposure. Semiconductor Industry Association, Nov. 2019, Appendix A, pp.14-15. Engineering controls and PPE employed to minimized exposure during container changeouts workers are presented in Semiconductor Industry Association, Nov. 2019, Appendix A, pp.6-8, pp.16-17, C-1 thru C-4.

- Occupationally non-exposed workers are the majority of workers in the fab. IH monitoring data was provided (Semiconductor Industry Association, Nov. 2019, Appendix A, p. 14, pp.17-18, F-1 thru F-6.).

- Training. Workers who may come into contact with chemicals must complete training prior to handling chemicals. Example personal protective equipment and glove training programs were provided to EPA (Semiconductor Industry Association, 2020. Appendix B; Intel, 2019; Intel, 2020). Do you need additional information on training programs?

- Cardno ChemRisk use of PBPK model and the basis for its output. Cardno-ChemRisk used EPA's PBPK model to prepare its own assessment of the occupational exposure of semiconductor workers. Modeling with refined exposure inputs and assumptions based on best available science shows no unreasonable risk to semiconductor workers. For clarification of the PBPK modeling, please refer to the attached supplemental information and the report which is found in Semiconductor Industry Association, 2020, Appendix A. If EPA personnel have questions, please advise.

- We concur with EPA's finding that the use of NMP in semiconductor manufacturing does not present an unreasonable risk of injury to the environment; therefore, we do not address those conclusions here. We note the discussions during SACC meeting and concerns were addressed in Intel's January 2020 comments (Intel, 2020).

- SIA considers all chemical-related exposures under the conditions of use in semiconductor manufacturing to be minimal such that no unreasonable risks are presented. This conclusion was reached by EPA in another recently released draft risk evaluation for a substance that generally poses a greater hazard than NMP.

- Our members would be happy to work with the Agency to fill any data gaps and in support of the conclusion that NMP in semiconductor manufacturing presents no unreasonable risk

**References**

**Semiconductor Industry Association, Nov. 2019**. Comments of the Semiconductor Industry Association (SIA) To the Science Advisory Committee on Chemicals (SACC) On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP), 84 Fed. Reg. 60,087 (Nov. 7, 2019) [EPA–HQ–OPPT–2019–0236; FRL–10001–87], Submitted November 26, 2019. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0031

**Intel, 2019**. Intel Comments to: Science Advisory Committee on Chemicals (SACC) On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP), December 5, 2019. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0037

**Semiconductor Industry Association, 2020**. Comments of the Semiconductor Industry Association (SIA) On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP); 84 Fed. Reg. 60,087 (Nov. 7, 2019); [EPA–HQ–OPPT–2019–0236; FRL–10001–87]; submitted January 21, 2020. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0052

**Intel, 2020**. Comments of Intel To the United States Environmental Protection Agency On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP); 84 Fed. Reg. 60,087 (Nov. 7, 2019) [EPA–HQ–OPPT–2019–0236; FRL–10001–87] Submitted January 21, 2020. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0064.

**OECD 2010**. Emission Scenario Document on Photoresist Use in Semiconductor Manufacturing. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2004)14/rev1&doclanguage=en.

# Supplemental Information

# Global Refinements of Draft US EPA Semiconductor Manufacturing Scenarios

| | EPA assumptions | Refined inputs |
|---|---|---|
| Glove Protection Factor | 10 | 20 (Industry workers handling chemicals must undergo glove training) |
| Dermal Loading | Skin immersion | 0.7 to 2.1 mg/cm2 |
| Surface area of liquid contact | One to two hands | Most work activities: 3 fingertips (central tendency) and 10 fingertips (high-end) |
| Dermal contact time | 360 to 720 minutes per shift | 20-60 minute per shift |
| Shift duration | 30 – 60 hours/week | 36 – 48 hours/week |
| Fraction of skin exposed to dermal vapor | 25% | <2% (Conservative industry assumption based on typical skin coverage) |
| Annual task frequency | 52 weeks per year | 50 weeks per year |

** NMP was not detected in a majority of personal air sampling, suggesting low potential for residual NMP-containing liquid to contact skin

# Non-Cancer Risk Estimate for Chronic Exposures Following Occupation Use of NMP

| Work Activity | Parameter | Glove protection factor | NMP weight fraction | Shift time (hr/d) | Shift frequency (d/wk) | Annual frequency (wks/yr) | Full shift NMP air concentration (mg/m3, TWA) | Skin surface area (cm2) | | Dermal contact time (hr) | Body weight (kg) | Annual average MOE | Benchmark MOE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Fab workers with NMP container change out | Central tendency (50th percentile) | 20 | 0.025 | 12 | 3 | 50 | 0.14 | 24.08 (m) | 20.03 (f) | 0.33 | 74 (f) 88 (m) | 7717 | 30 |
| | High end (95th percentile) | 20 | 0.5 | 12 | 4 | 50 | 0.41 | 80.25 (m) | 66.75 (f) | 1.0 | | 1883 | 30 |

Under EPA assumptions, MOEs indicated the potential for unreasonable risk.

# Non-Cancer Risk Estimate for Chronic Exposures Following Occupation Use of NMP

| Work Activity | Parameter | Glove protection factor | NMP weight fraction | Shift time (hr/d) | Shift frequency (d/wk) | Annual frequency (wks/yr) | Full shift NMP air concentration (mg/m3, TWA) | Skin surface area (cm2) | | Dermal contact time (hr) | Body weight (kg) | Annual average MOE | Benchmark MOE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Maintenance | Central tendency (50th percentile) | 20 | 0.5 | 12 | 3 | 50 | 0.02 | 267.5 (m) | 222.5 (f) | 0.33 | 74 (f) 88 (m) | 4151 | 30 |
| | High end (95th percentile) | 20 | 1 | 12 | 4 | 50 | 0.70 | 374.5 (m) | 311.5 (f) | 1.0 | | 298 | 30 |

Under EPA assumptions, MOEs indicated the potential for unreasonable risk.

# Discussion

- In the US EPA's draft risk assessment, dermal exposure to liquid NMP was the major contributor to the determination of unreasonable risk
  - Inhalation and dermal vapor exposures had negligible contributions to the unreasonable risk determination

- Dermal liquid contact is unlikely to be the dominant source of NMP exposure for workers in the semiconductor industry:
  - IH data indicate a low potential for exposure to NMP based on well-described work and maintenance practices supported by air sampling data
  - There are generally limited opportunities for skin contact with NMP-containing liquids due to operational conditions, engineering controls, administrative controls and PPE
  - A glove PF of 20 (95% efficiency) is appropriate because employees are provided with comprehensive glove training and due to the strict work rules and procedures that must be adhered to in the semiconductor industry
  - Prolonged skin contact with NMP can cause dermatitis, blistering or cracking of skin, thus prolonged contact (1 or 2 hands immersed in solvent for 30-60 hr/wk) assumed in the US EPA draft risk assessment is self-limiting and thus implausible

## Conclusion

- The US EPA's preliminary conclusion of unreasonable risk for the use of NMP in semiconductor manufacturing reflected a lack of refinement and use of incorrect assumptions in the draft risk assessment
  - 1 or 2 hands immersed in concentrated NMP for 360 to 720 minutes per shift

- Using refined exposure scenarios based on IH monitoring data provided by the industry as well as more accurate work task descriptions, **acute and chronic MOEs were greater than 30 indicating that the use of NMP in the semiconductor industry does not present unreasonable risk**

# Appendix

# Main Refinements to Exposure Scenarios

| Exposure scenario | Specific refinement(s) |
|---|---|
| Typical fab worker | Surface area potentially exposed to NMP: none |
| Fab worker with NMP container change out | NMP weight percent of 2.5% (central tendency) and 5% (high-end) |
| Maintenance | Surface area potentially exposed to NMP-containing liquid: 50% - 70% of the palm side of both hands (Note: Workers wear chemical resistant PPE and these exposures are not expected to occur) |
| Virgin NMP truck unloading | Surface area potentially exposed to NMP-containing liquid: 10 finger tips (central tendency) to 50% of the palm (high end) (Note: Workers wear chemical resistant PPE and these exposures are not expected to occur)<br>Weekly shift frequency: 1 day per week (8 hr shift)<br>Annual frequency: 1 week per year |
| Waste truck loading | Surface area potentially exposed to NMP-containing liquid: 10 finger tips (central tendency) to 50% of the palm (high end) (Note: Workers wear chemical resistant PPE and these exposures are not expected to occur)<br>Weekly shift frequency: 1 day per week (8 hr shift)<br>Annual frequency: once per month (central tendency) or once every three weeks (high end) |

# Table 5-1: Summary of PBPK modeling parameters for worker inhalation exposures [updates US EPA (2019a) Table 2-31]

| Work Activity | Parameter Characterization | Shift Time (hours/day) | Shift Frequency (days/week) | Annual Frequency (weeks/year) | Number of samples | Full-Shift NMP Air Concentration ($mg/m^3$, TWA) | Source |
|---|---|---|---|---|---|---|---|
| Container handling, small containers | Central tendency ($50^{th}$ percentile) | 12 | 3 | 50 | 14 | 0.51 | SIA, 2019a |
| | High-end ($95^{th}$ percentile) | 12 | 4 | 50 | | 0.61 | SIA, 2019a |
| Container handling, drums | Central tendency ($50^{th}$ percentile) | 12 | 3 | 50 | 10 | 0.013 | SIA, 2019a |
| | High-end ($95^{th}$ percentile) | 12 | 4 | 50 | | 1.6 | SIA, 2019a |
| Typical fab worker | Central tendency ($50^{th}$ percentile) | 12 | 3 | 50 | 28 | 0.14 | SIA, 2019a |
| | High-end ($95^{th}$ percentile) | 12 | 4 | 50 | | 0.41 | SIA, 2019a |
| Fab worker w/ NMP container changeout | Central tendency ($50^{th}$ percentile) | 12 | 3 | 50 | 28 | 0.14 | SIA, 2019a |
| | High-end ($95^{th}$ percentile) | 12 | 4 | 50 | | 0.41 | SIA, 2019a |
| Maintenance | Central tendency ($50^{th}$ percentile) | 12 | 3 | 50 | 36 | 0.02 | SIA, 2019a |
| | High-end ($95^{th}$ percentile) | 12 | 4 | 50 | | 0.70 | SIA, 2019a |
| Virgin NMP truck unloading | Central tendency ($50^{th}$ percentile) | 8 | 1 | 1 | 1 | 4.8 | SIA, 2019a |
| | High-end ($95^{th}$ percentile) | 8 | 1 | 1 | | 4.8 | SIA, 2019a |
| Waste truck loading | Central tendency (Single sample) | 8 | 1 | 12 | 1 | 0.72 | SIA, 2019a |
| | High-end (Single sample) | 8 | 1 | 17.3 | | 0.72 | SIA, 2019a |

# Table 5-2: Summary of worker dermal liquid exposure parameters [updates US EPA (2019a) Table 2-32]

| Work Activity | Parameter Characterization | Glove Protection Factor | NMP Weight Fraction | Shift Frequency | Annual Frquency | Skin Surface Area Exposed [b] | | Dermal Contact Time | Body Weight |
|---|---|---|---|---|---|---|---|---|---|
| | | | Unitless | (days/ week) | (weeks/ year) | Male ($cm^2$) | Female ($cm^2$) | (h) | (kg) |
| Container handling, small containers | Central tendency (50th percentile) | 20 | 0.6 | 3 | 50 | 24.08 | 20.03 | 0.33 | 74 (f) 88 (m) |
| | High-end (95th percentile) | 20 | 0.75 | 4 | 50 | 80.25 | 66.75 | 1.00 | |
| Container handling, drums | Central tendency (50th percentile) | 20 | 0.5 | 3 | 50 | 24.08 | 20.03 | 0.33 | 74 (f) 88 (m) |
| | High-end (95th percentile) | 20 | 0.75 | 4 | 50 | 80.25 | 66.75 | 1.00 | |
| Typical fab worker | Central tendency (50th percentile) | 20 | N/A | 3 | 50 | 0.0 | 0.0 | 0.00 | 74 (f) 88 (m) |
| | High-end (95th percentile) | 20 | N/A | 4 | 50 | 0.0 | 0.0 | 0.00 | |
| Fab worker w/ NMP container changeout | Central tendency (50th percentile) | 20 | 0.025 | 3 | 50 | 24.08 | 20.03 | 0.33 | 74 (f) 88 (m) |
| | High-end (95th percentile) | 20 | 0.05 | 4 | 50 | 80.25 | 66.75 | 1.00 | |
| Maintenance | Central tendency (50th percentile) | 20 | 0.5 | 3 | 50 | 267.5 | 222.5 | 0.33 | 74 (f) 88 (m) |
| | High-end (95th percentile) | 20 | 1 | 4 | 50 | 374.5 | 311.5 | 1.00 | |
| Virgin NMP truck unloading | Central tendency (Single sample) | 20 | 1 | 1 | 1 | 80.25 | 66.75 | 0.33 | 74 (f) 88 (m) |
| | High-end (Single sample) | 20 | 1 | 1 | 1 | 267.5 | 222.5 | 1.00 | |
| Waste truck loading | Central tendency (Single sample) | 20 | 0.92 | 1 | 12 | 80.25 | 66.75 | 0.33 | 74 (f) 88 (m) |
| | High-end (Single sample) | 20 | 0.92 | 1 | 17.3 | 267.5 | 222.5 | 1.00 | |

# Table 5-4: PBPK model input parameters [updates US EPA (2019a) Table 2-34]

| Work Activity | Scenario | Full-Shift NMP Air Concentration | NMP Weight Fraction | Shift time | Shift Frequency | Annual Frequency | Glove Protection Factor | Skin Surface Area Exposed | | Dermal Contact Time | Body Weight |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | (mg/m³, TWA) | Unitless | (hours/ day) | (days/ week) | (weeks/ year) | | Male ($cm^2$) | Female ($cm^2$) | (h) | (kg) |
| Container handling, small containers | Central Tendency | 0.511 | 0.6 | 12 | 3 | 50 | 20 | 24.08 | 20.03 | 0.33 | 74 (f) 88 (m) |
| | High-end | 0.613 | 0.75 | 12 | 4 | 50 | 20 | 80.25 | 66.75 | 1.00 | |
| Container handling, drums | Central Tendency | 0.013 | 0.5 | 12 | 3 | 50 | 20 | 24.08 | 20.03 | 0.33 | 74 (f) 88 (m) |
| | High-end | 1.557 | 0.75 | 12 | 4 | 50 | 20 | 80.25 | 66.75 | 1.00 | |
| Typical fab worker | Central Tendency | 0.139 | N/A | 12 | 3 | 50 | 20 | 0.00 | 0.00 | 0.00 | 74 (f) 88 (m) |
| | High-end | 0.409 | N/A | 12 | 4 | 50 | 20 | 0.00 | 0.00 | 0.00 | |
| Fab worker w/ NMP container changeout | Central Tendency | 0.139 | 0.025 | 12 | 3 | 50 | 20 | 24.08 | 20.03 | 0.33 | 74 (f) 88 (m) |
| | High-end | 0.409 | 0.05 | 12 | 4 | 50 | 20 | 80.25 | 66.75 | 1.00 | |
| Maintenance | Central Tendency | 0.020 | 0.5 | 12 | 3 | 50 | 20 | 267.50 | 222.50 | 0.33 | 74 (f) 88 (m) |
| | High-end | 0.696 | 1 | 12 | 4 | 50 | 20 | 374.50 | 311.50 | 1.00 | |
| Virgin NMP truck unloading | Central Tendency | 4.822 | 1 | 8 | 1 | 1 | 20 | 80.25 | 66.75 | 0.33 | 74 (f) 88 (m) |
| | High-end | 4.822 | 1 | 8 | 1 | 1 | 20 | 267.50 | 222.50 | 1.00 | |
| Waste truck loading | Central Tendency | 0.715 | 0.92 | 8 | 1 | 12 | 20 | 80.25 | 66.75 | 0.33 | 74 (f) 88 (m) |
| | High-end | 0.715 | 0.92 | 8 | 1 | 17.3 | 20 | 267.50 | 222.50 | 1.00 | |

# Table 5-5: Non-cancer risk estimates for chronic exposures [updates US EPA (2019a) Table 4-28]

| Work Activity | Health Effect, Endpoint and Study | Chronic POD, AUC (hr mg/L) | Scenario | Weekly Average Chronic Exposure, AUC (hr mg/L) | Annual Frequency (weeks /year) | Annual Average Chronic Exposure, AUC (hr mg/L) | Annual Average MOE | Benchmark MOE |
|---|---|---|---|---|---|---|---|---|
| Container handling, small containers | Reproductive Effects Decreased Fertility (Exxon, 1991) | 183 | Central Tendency | 0.09 | 50 | 0.09 | 2018 | 30 |
| | | | High-end | 0.22 | 50 | 0.21 | 864 | 30 |
| Container handling, drums | Reproductive Effects Decreased Fertility (Exxon, 1991) | 183 | Central Tendency | 0.01 | 50 | 0.01 | 31345 | 30 |
| | | | High-end | 0.44 | 50 | 0.43 | 430 | 30 |
| Typical fab worker | Reproductive Effects Decreased Fertility (Exxon, 1991) | 183 | Central Tendency | 0.02 | 50 | 0.02 | 7777 | 30 |
| | | | High-end | 0.10 | 50 | 0.09 | 1983 | 30 |
| Fab worker w/ NMP container changeout | Reproductive Effects Decreased Fertility (Exxon, 1991) | 183 | Central Tendency | 0.02 | 50 | 0.02 | 7717 | 30 |
| | | | High-end | 0.10 | 50 | 0.10 | 1883 | 30 |
| Maintenance | Reproductive Effects Decreased Fertility (Exxon, 1991) | 183 | Central Tendency | 0.05 | 50 | 0.04 | 4151 | 30 |
| | | | High-end | 0.64 | 50 | 0.61 | 298 | 30 |
| Virgin NMP truck unloading | Reproductive Effects Decreased Fertility (Exxon, 1991) | 183 | Central Tendency | 0.20 | 1 | 0.004 | 48186 | 30 |
| | | | High-end | 0.27 | 1 | 0.01 | 34727 | 30 |
| Waste truck loading | Reproductive Effects Decreased Fertility (Exxon, 1991) | 183 | Central Tendency | 0.04 | 12 | 0.01 | 22160 | 30 |
| | | | High-end | 0.11 | 17.3 | 0.04 | 5179 | 30 |

# Table 5-6: Non-cancer risk estimates for acute exposures [updates US EPA (2019a) Table 4-27]

| Work Activity | Health Effect, Endpoint and Study | Acute POD, $C_{max}$ (mg/L) | Scenario | Acute Exposure, Peak Blood Concentration (mg/L) | MOE | Benchmark MOE |
|---|---|---|---|---|---|---|
| Container handling, small containers | Developmental Effects Increased Fetal Resorptions (Saillenfait et al., 2003) | 216 | Central Tendency | 0.02 | 13107 | 30 |
| | | | High-end | 0.04 | 5169 | 30 |
| Container handling, drums | Developmental Effects Increased Fetal Resorptions (Saillenfait et al., 2003) | 216 | Central Tendency | 0.004 | 60090 | 30 |
| | | | High-end | 0.05 | 4223 | 30 |
| Typical fab worker | Developmental Effects Increased Fetal Resorptions (Saillenfait et al., 2003) | 216 | Central Tendency | 0.004 | 48496 | 30 |
| | | | High-end | 0.01 | 16931 | 30 |
| Fab worker w/ NMP container changeout | Developmental Effects Increased Fetal Resorptions (Saillenfait et al., 2003) | 216 | Central Tendency | 0.004 | 48448 | 30 |
| | | | High-end | 0.01 | 16749 | 30 |
| Maintenance | Developmental Effects Increased Fetal Resorptions (Saillenfait et al., 2003) | 216 | Central Tendency | 0.039 | 5489 | 30 |
| | | | High-end | 0.23 | 942 | 30 |
| Virgin NMP truck unloading | Developmental Effects Increased Fetal Resorptions (Saillenfait et al., 2003) | 216 | Central Tendency | 0.141 | 1536 | 30 |
| | | | High-end | 0.20 | 1067 | 30 |
| Waste truck loading | Developmental Effects Increased Fetal Resorptions (Saillenfait et al., 2003) | 216 | Central Tendency | 0.025 | 8781 | 30 |
| | | | High-end | 0.15 | 1417 | 30 |